

# Minimal breaches of confidentiality in health care research: a Canadian perspective

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## Author's abstract

*In a large proportion of health care research based on the retrospective review of records, minimal breach of patient confidentiality appears to be inevitable. This occurs at initial identification of and access to the chart, selected on the basis of the condition under investigation, and while individual identifiability can be blocked at subsequent stages, at this point it does occur. Prospective individual consent is impractical because often neither the desirability nor the specific subject of the research is known at the time of making the record, and retrospective patient tracing to obtain it is often impossible. I argue that the benefit of the research outweighs the minimal breach of confidentiality, and that in my own jurisdiction, this appears to be envisaged and accepted in Canadian law.*

The patient's right to confidentiality of his/her individual health care information can be derived in various ways from ethical principles; the most common is from the right to autonomy, and to the information necessary for autonomous decision-making. Information acquired in the process of health care is in this sense under the control of the patient, and is held confidential and accessible only to those with a 'need-to-know', to fulfil their function in the health care team. Who actually owns the information is legally unclear in Canada; the chart is the property of the hospital or physician, but the patient has the right of free and unimpeded access to it, except in the rare situation in which knowledge of the record might be damaging to the patient. 'Information is held in a fashion somewhat akin to a trust', as part of the doctor's fiduciary duty (1). Ethically, one might deem the record the property of the patient. Some jurisdictions also adduce a specific and general right to privacy, but this is not so in Canada. Communication of information outside the 'need-to-know for treatment' situation, may be required or permitted by statute; otherwise, as in research, it depends on the consent of the patient being given.

The value placed upon confidentiality varies. Kottow (2) believes it to be absolute and unmodifiable, which appears to me ethically dubious and unrealistic in practical terms. Others, including myself, have discussed the modifications and limitations of confidentiality (3,4), which are partly statutory. In research proposals and procedures in health care, consent given on a signed form is generally required. These must promise observation of the principle of confidentiality, and state any modifications to it; for example, access to the chart by representatives of firms providing experimental drugs, or other agencies. This extends to the individual being unidentifiable in published material, either specifically or by inclusion in a limited cohort.

There is one type of health care research in which confidentiality is commonly breached, to a minimal extent, without either the specific consent or knowledge of the patient. This occurs when research is upon a specific condition – let me term this 'X' – and is done by review of health care records. Peptic ulcer is an example. The investigator may study its aetiology, pathogenesis, age, sex and geographical distribution in the population, response to therapy and outcome. Such research is chart-based and initially involves identification of patients with condition X. Except in the rare circumstances in which the database is separated, with a barrier to linkage of data identifying the individual with the rest of the chart, this initial step inevitably involves gaining knowledge of the patient's identity. Following chart acquisition, data relevant to the study are either recorded in anonymous, unlinkable form, or linkage to the individual's identity is blocked by coding which can be broken only in special circumstances.

It is theoretically possible to create health care records in which all the data except names are stored, and the linkage with a name requires a specific step and password. This implies computerised storage of the whole chart, which is a reality only in a very few institutions, and a system designed with anonymity in mind, which is not in itself difficult. This is a possibility for the future; in present systems, the data which researchers need are stored on paper and identified by name.

## Key words

Confidentiality; research; minimal breach; consent.

This type of health care research is common, and rarely the subject of specific individual consent, which would be very difficult to secure. Research is commonly retrospective, and may extend back a long time. In cancer of the breast, for example, recurrence twenty years after initial treatment is not uncommon. The condition on which research is desired, and the object of the research, are often unknown at the time of generation of the chart. General consent given at the time of admission to chart research would necessarily be so non-specific as to be of dubious value and validity.

If we accept the desirability of such research, the breach of confidentiality without consent is inevitable but can be minimised. But however limited the breach is, is it legitimate? One factor which must be considered is the likelihood and degree of injury to the patient. This 'injury' is commonly confined quite simply to the occurrence of the breach of confidentiality, the mere fact that it has happened. No actual damage to the patient results. The patient is not identified to anyone other than the researcher, and this briefly, nor is he identifiable in published work. Such 'damage' might be regarded as theoretical rather than actual, and Canadian jurisdictions are very reluctant to admit such damages.

But the fact of the breach of confidence remains, and its significance must be assessed. Is its mere occurrence damaging? This is rather like the old question: 'If a tree falls in the forest and no one is there, does it make a noise?'

### **Detrimental information**

Much more rare, and more serious, is the acquisition and communication of information detrimental to the patient. Let us suppose that a research assistant recognises the chart as that of a neighbour, and notices that she had an abortion when her husband, his friend, had been overseas on military duty for six months. The research assistant communicates this information outside his professional relationship, and the patient suffers; shame, obloquy, possibly assault and/or divorce. Significant damage results from this breach of confidentiality, and no consent has been given to the research.

This is so serious a possibility that it must be considered seriously, but there are modifying factors. First, the risk appears very much less than that of unauthorised communication of information derived in the ordinary course of health care, with which we are much more familiar, and against which we guard as strictly as possible. The public has minimal knowledge of the extent to which health care information is disseminated and utilised in normal practice. This does not appear to be a matter of deep concern, save when breach of confidence results in significant damage, in such conditions as mental illness, conditions related to sexual activity,

HIV infection and AIDS. This is because the patient is rarely disadvantaged by such dissemination. The risk of communication of information acquired by researchers from patients' charts is in fact so rare that I have no knowledge of a legal action arising from such circumstances, in Canada. This is not to say that it does not exist but that our society does not express it in this way; it seems to be likely that actions would arise, if it occurred.

Secondly, the very slight risk of damage to the patient must be balanced against benefit to the community from the research. Such risk/benefit considerations in confidentiality are by no means new; they are used in deciding whether there should be compulsory reporting of such matters as child abuse, of statements by patients indicating that they are a risk to others (5), and of diseases which may render a person a public risk when engaged in such activities as driving a vehicle or piloting an aircraft. The legal trend in Canada has been to place more weight on the public good, and less on that of the individual to absolute confidentiality. In the research situation the future benefit is hypothetical and unquantifiable, but none the less it exists, else why do the research?

Public sensitivity has been expressed in related situations in which there is no breach of confidentiality, such as research upon the anonymous unlinkable surplus specimens of blood derived in the routine course of health care practice. Demands have been made for a right to 'opting-out', and to the exclusion of a person's surplus blood specimen from investigation of prevalence of viral antibodies in the population (6,7). It is very significant that this only arose when such studies were undertaken on HIV; they had in fact been done for a century on such viruses as those of influenza, mumps, measles and chickenpox without any murmur of public interest, let alone objection. The practice of what is generally termed 'public health' depends very largely upon such studies, and was significantly retarded because of the new concern (8). Surplus blood specimens are also used for such essential purposes as establishing ranges of normal values for their various constituents, upon which the practice of medical biochemistry depends. My own opinion is that this was an emotional and illogical reaction, with no basis in ethics, and that there is no ethical right nor should there be a legal one to such 'opting-out' (9), but there was for a time a limited public furore which now seems to have subsided. The existence of such reactions, despite their lack of basis in ethics or logic, and their emotional foundation, must be recognized.

What then should be our ethical position with regard to chart-based research? Is the necessary minimal breach of confidentiality without consent, more than balanced by the public good which results from such research? I think it is; unless a very great weight is put upon the mere fact of the breach, there is no 'damage' to the patient, and great good to

society. It can be argued that society should be informed of what is going on, as was stated for research upon surplus blood specimens; certainly this information should be available, but as I have said before, it is hard to conceive of its generating great public interest.

The groundswell from the grassroots sets its own priorities, and this does not seem to figure among them. It can be argued that sheer lack of public interest is in itself a form of implied general consent.

Ethics and law do overlap, and a partial definition of law, is that it is one way in which a society expresses its ethical beliefs. All law is based on ethics, but all ethics is not expressed in law (10). The beliefs so expressed, will be those on which there is general agreement, and which are regarded as sufficiently important to be stated in this way. In Canada, the law might deal with this issue federally, as in the criminal code, or more probably provincially, as a statute or regulation under an act. In my own small province of Saskatchewan, there are two statutes which might be interpreted as legalising such research, though to my knowledge they have never been put to any test. They are quoted for interest, comparison and possible example; they may be construed as expressing society's belief that such research is justified and should be encouraged, and as condoning the necessary, minimal breach of confidentiality.

### Disclosure for academic purposes

The Hospital Standards Act deals with the operation of hospitals, and in the regulations made under it there appears the following:

'The health record ... shall remain confidential ... except that it *shall* be disclosed under the following circumstances' (details follow). 'It *may*' (emphasis mine) 'be disclosed under the following circumstances ... for academic ... purposes ... to the medical staff of the hospital or to any committee thereof' (11).

If this was ever subject to judicial interpretation, the following issues might be raised. Is 'confidential' absolute or relative? What does 'academic' mean? The University of Saskatchewan interprets it as teaching and research with the addition of practice or service in some colleges, including medical colleges. Chart-based research of the sort described is very common and often the basis of published papers in peer-reviewed journals. It is a commonly accepted practice in modern scientific medicine; such published papers are cited in faculty members' *curriculum vitae*, and used in their assessment for promotion, tenure, sabbatical leave and general academic advancement.

The second statute is the Local Authority Freedom of Information and Privacy Act of

Saskatchewan (12), passed but at the time of writing not yet promulgated for health care institutions. (My personal information is that this delay has been granted so that the institutions may have time to set up their procedures for the new workload.) This Act defines a hospital as a local authority, defines the head thereof, and deals with health care research as follows. 'Personal information' includes 'information that relates to health care that has been received by the individual or to the health history of the individual'. Personal information 'may be disclosed (by the head) ... to any person or body for research or statistical purposes if the head: (i) is satisfied that the purpose for which the information is to be disclosed is not contrary to the public interest and cannot reasonably be accomplished unless the information is provided in a form that would identify the individual to whom it relates; and (ii) obtains from the person or body a written agreement not to make a subsequent disclosure of the information in a form that could reasonably be expected to identify the individual to whom it relates'.

In these statutes, the society of which I am a member seems to have expressed its agreement with my resolution of the ethical problem discussed above, and with the balance of values. Chart-based research, and its necessary minimal breach of confidentiality without consent, is ethically justified by its negligible damage to the patient, and its positive contribution to the public good. Society places certain limitations upon freedom of access to charts, by limiting it and requiring a formal pledge that confidentiality will be respected subsequent to the initial, condoned breach. The researcher is safeguarded against legal action unless information is divulged in an improper way and identifiable form.

With these statutes in place, it does not seem necessary or desirable to seek to secure specific consent from the individual patient, as in a consent form to possible future chart-based research signed on admission.

The sensitivity of society to ethical issues in health care is a relatively modern development; one of the things it does, is make us examine in a new light, our common practices and traditional behaviour. In this example, we seem to be doing the right thing.

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### References

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- (4) Emson H E. Limits to confidentiality. *Journal of the Society of Obstetricians and Gynaecologists of Canada* 1992; 14: suppl: 34-37.
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- (8) Anonymous [editorial]. Anonymous HIV testing. *Lancet* 1990; 335: 575-576.
- (9) Emson H E. The ethics and legality of HIV prevalence studies. *Health law in Canada* 1992; 12: 95-96.
- (10) Lord Chief Justice Coleridge in R v Instan: 'It would not be correct to say that every moral obligation involves a legal duty; but every legal duty is founded on a moral obligation'. 1 QB 450, at 453.
- (11) Saskatchewan regulation 331/79, s (16) (1) and (2) (e).
- (12) Saskatchewan Local Authority Freedom of Information and Privacy Act 1990-1991: ch L-27.1; sections 23 (1) (c) and 28 (1) (k) (i) and (ii).

## News and notes

### Wood Institute Research fellowships

The seven recipients of the 1994 Wood Institute Research fellowships awarded by the College of Physicians of Philadelphia are: Paul Berman, MD, *The Medical Mutual Improvement Society in America, 1720-1835*; Deborah Franklin, University of Pennsylvania, *Controlling the Atom: the Impact of Ionizing Radiation on Human Health, 1895-1942*; Jennifer Gunn, University of Pennsylvania, *Controlling the Population: Ideological Links among Contraception, Life Extension, Public Health, and Population Policy*; Lisa Herschbach, Harvard University, *The Hidden Civil War: Medical and Literary Narratives from the Turner's Lane Hospital*; David McCarter, University of Iowa, *Medical Ideas and the Popular Press in New England, 1680-1820*; Jeffrey A Mullins, Johns Hopkins University, *The Moral Mind: Agency, Psychology, and the Mind-Body Connection in American Thought, 1790-1860*, and Allison Pingree, Harvard University, *'It's Two that Makes the Trouble': Figures of Replication in the Fiction of Mark Twain, Sherwood Anderson, Eudora Welty, and Carson McCullers*.

Established in 1787, the College of Physicians of Philadelphia is one of the oldest honorary, private medical academies in the United States. The resources of this not-for-profit institution include a renowned Library, the Mutter Museum and the Francis C Wood Institute for the History of Medicine. The Wood Institute fellowship programme enables scholars to spend time in residence at the college in order to use its library and museum. The fellowship programme is partially supported by the Women's Committee of the College of Physicians, and supports research in the history of medicine.

The 1994 Scholar-in-Residence fellowship of the Wood Institute for the History of Medicine goes to Dr David M Cantor. Dr Cantor received his BA and PhD from the University of Lancaster, and is currently a Research Fellow in the Department of the History of Science, Medicine, and Technology at Johns Hopkins University. He will be researching Neo-Hippocratism in Inter-War British Medicine.